

REMARKS

In the Office Action, claims 1, 3, 4, 6, 7, 18, 19, 21-23 and 25 are rejected under 35 U.S.C. § 102 as allegedly anticipated by WO 92/11046; and claims 1-7 and 15-16 are rejected under 35 U.S.C. § 103 as allegedly unpatentable over U.S. Patent No. 5,383,324 (“*Segers*”) in view of U.S. Patent No. 4,784,495 (“*Jonsson*”). Applicants believe that the rejections are improper based on the reasons set forth below.

With respect to the anticipation rejection in view of WO 92/11046, claims 1 and 16 are the sole independent claims at issue. Claim 1 recites a cartridge that has inlet and an outlet, for connection in-line in the hemodialysis machine for passage of water, or solution through the cartridge. The cartridge contains sodium bicarbonate in solid form, and a component selected from the group consisting of an acid, an acid anhydride in solid form and carbon dioxide gas in an amount to prevent a temporary increase in pH of a dialysis solution produced utilizing the cartridge.

Claim 16 recites a hemodialysis machine that includes a cartridge having an inlet and an outlet for connection in-line in a hemodialysis machine. The cartridge contains sodium bicarbonate in solid form, and a component selected from the group consisting of an acid, an acid anhydride in solid form, and carbon dioxide gas in an amount to prevent a temporary increase in pH of a dialysis solution produced utilizing the cartridge.

When the cartridge is mounted in the hemodialysis machine and water is passed through the cartridge, the acid or anhydride (including carbon dioxide) is gradually dissolved, decreasing the pH of the resulting solution to counteract any temporary increase in pH caused by sodium carbonate contamination. This facilitates the in-line administration of sodium bicarbonate during dialysis.

In contrast, the cited art is deficient with respect to at least a number of features of the claimed invention. The cited reference generally provides an on-site dialysate production system for supplying dialysate to a hemodialysis system. However, it utilizes dry chemical pellets that are added to mixing chambers and then dissolved in water to form the dialysate. The mixed dialysate then flows from the chambers into the dialysate circuit. See, WO 92/11046, page 2, lines 1-12.

This clearly contrasts the claimed invention. Indeed, the claimed invention provides a cartridge that has an openable sealed inlet and an openable sealed outlet for connection in-line in

a hemodialysis machine for passage of water or solution through the cartridge wherein the cartridge contains sodium bicarbonate in solid form. Nowhere does the cited art disclose or arguably suggest a cartridge with inlet and outlet features that contain sodium bicarbonate in solid form as claimed. Indeed, the cited art first dispenses the dry chemical pellets to a mix chamber where the dialysis solution is formed in batch amounts as illustrated, for example, in Figure 2 of WO 92/11046. Clearly, this is deficient with respect to the in-line features as further required by the claimed invention.

Based on at least these differences, Applicants believe that the cited art fails to disclose or arguably suggest the claimed invention. Therefore, Applicants respectfully submit that the cited art fails to anticipate or arguably render obvious the claimed invention.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

With respect to the obviousness rejection in view of *Segers* and *Jonsson*, claims 1 and 16 are the sole independent claims at issue. Claim 1 recites a cartridge and claim 16 recites a hemodialysis machine as previously discussed.

Again, the claimed invention provides a cartridge that has both an openable sealed inlet and an openable sealed outlet for connection in-line in a hemodialysis machine for passage of water or a solution through the cartridge wherein the cartridge contains sodium bicarbonate in solid form. The cartridge additionally contains a component, such as an acid or an acid anhydride in solid form or carbon dioxide gas. When the water is passed through the cartridge in-line, the acid, acid anhydride or carbon dioxide is gradually dissolved, thus decreasing the pH of the resulting solution to counteract any temporary increase in pH caused by sodium carbonate contamination. Thus, the in-line administration of a sodium bicarbonate solution during dialysis can be facilitated. Applicants have provided a number of experiments to demonstrate the beneficial effects of the claimed invention as disclosed, for example on pages 4-6 of Applicants' Specification.

In contrast, Applicants believe that the cited art is deficient with respect to the claimed invention. Indeed, the primary *Segers* reference fails to provide a cartridge with in-line capabilities to administer a sodium bicarbonate solution during hemodialysis as claimed. Indeed, the primary focus of *Segers* relates to a method and device for stabilizing and storing bicarbonate solutions. In general, *Segers* utilizes carbon dioxide to stabilize the bicarbonate solutions. More

specifically, *Segers* discloses that carbon dioxide pressures of 80 mmHg and greater can be used to stabilize the bicarbonate solution. See, *Segers*, column 4, lines 50-69.

Indeed, *Segers* is directed to a problem in the art that is completely different from the one addressed by the present invention as it relates to the use of cartridges. In this regard, the pH of the mixed dialysis solution is monitored upstream of the dialyzer. If the pH falls outside a given range, then an alarm is triggered. It has been found that this often happens during the first twenty minutes of flow, when the machine is being setup for operation. After this period, no problems are typically encountered. This can cause substantial inconvenience to personnel operating hemodialysis machines, since the problem has to be investigated and the machine reset each time the alarm is triggered. See, Specification, page 1, lines 21-27.

The present inventors have discovered that the problem is probably caused by contamination of the sodium bicarbonate powder with a small amount of sodium carbonate. The bicarbonate is less soluble than the carbonate, so that a high pH is caused by the dissolution of the carbonate in the early stages. Once the carbonate has dissolved, the problem disappears. It is, however, difficult and expensive to produce a sodium bicarbonate powder which is not contaminated with sodium carbonate.

As previously discussed, the claimed invention provides a cartridge that has an openable sealed inlet and outlet for connection in-line in a hemodialysis machine for passage of water or solution through the cartridge which contains sodium bicarbonate in solid form and additionally contains an acid, an acid anhydride in solid form or carbon dioxide gas. During in-line applications, this allows the acid component to dissolve, thus decreasing the pH of the resulting solution to counteract any temporary increase in pH caused by sodium carbonate contamination. Therefore, the claimed invention provides a relatively easy and simple solution to this specific type of problem generally associated with cartridges and sodium bicarbonate. Again, Applicants have conducted a number of experiments to demonstrate the beneficial effects of the claimed invention. Therefore, Applicants believe that *Segers*, on its own is clearly deficient with respect to the claimed invention.

Further, Applicants do not believe that the Patent Office can rely solely on *Jonsson* to remedy the deficiencies of *Segers*. In this regard, the Patent Office merely relies on *Jonsson* for its purported teachings regarding the use of a cartridge. Indeed, *Jonsson* does not even specify whether the cartridge can be used for sodium bicarbonate in solid form, let alone in combination

with an acid, an acid anhydride or carbon dioxide as claimed. Therefore, Applicants do not believe that one skilled in the art would be inclined to modify the cited art to arrive at the claimed invention.

Based on at least these differences between the cited art and the claimed invention, Applicants believe that the cited art fails to disclose or suggest the claimed invention. Therefore, Applicants respectfully submit that the cited art, even if combinable, fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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